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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE		
	Application Number	09/735,995
	Filing Date	14 December 2000
	Named Inventor	Mark T. KEATING
	Group Art Unit	J.E. Souaya
	Examiner Name	1634
	Attorney Docket Number	2323-156
Title of the Invention:	MUTATIONS IN AND GENOMIC STRUCTURE OF HERG - A LONG QT SYNDROME GENE	

RESPONSE TO RESTRICTION REQUIREMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

With respect to the Restriction Requirement mailed 9 March 2002, Applicants believe that the restriction between the four groups as set forth is proper. Accordingly, Applicants hereby elect Group III, claims 22-25, for examination.

Applicants traverse the requirement to elect 5 mutations for examination, allegedly on the basis that more would pose an undue burden on the Examiner. Applicants do not believe that the examination of all of the mutations would be unduly burdensome.

Initially, Applicants note that all of the mutations were examined in the parent application, the claims of which were directed to nucleic acids encoding the mutations. Since all of the mutations were examined in the parent application, there must not have been undue burden on the Examiner to examine all the mutations.

Secondly, it is submitted that the examination of all of the mutations with respect to Group III does not present an undue burden for the examination of the claimed invention. The examination entails various aspects. First is a decision concerning utility under 35 U.S.C. §101. Although each mutant species being claimed is distinct, they are all related in their structure and biological activity. Consequently, a decision concerning utility will be identical for all of the species, and there is no added burden of examining all of the species as compared to examining only a single species.

The second aspect of examination is whether the provisions of the various paragraphs of 35 U.S.C. § 112 have been met. In general, and in this case, this means reviewing the application and claims for compliance with the provisions of paragraphs 1 and 2 of § 112. As for the enablement

aspect as found in paragraph 1 of § 112, all of the peptides are related in their structure and biological activity. Since no basis for distinguishing between the enablement of one species vs. another species has been set forth, it is presumed that all of the listed mutants will be treated equally. Again, this means that only a single decision needs to be made concerning all of the mutants. Therefore, this aspect of the examination will not be a serious burden if all mutants, vs. only one of the mutants, are examined.

Concerning paragraph 2 of § 112, this involves the wording of the claims. The wording of the claims in each Group is identical except for the specified mutant. Consequently, any objections to the language of the claims for one Group of claims is equally applicable to the other Groups of claims. Therefore, there is no increase in the burden concerning 35 U.S.C. § 112, second paragraph, if all mutants are examined.

The third aspect of examination is a review of prior art to determine whether the claims are anticipated or obvious. There are two aspects of such a search. A first aspect is a review of the prior art literature and patents. The literature to be reviewed will be identical for all of the mutants. All of the claimed mutants have similar, though not identical, structures and all are claimed to have the same utility. The Examiner has not stated that a search of the scientific literature will be any different for one mutant than for any other mutant. The Office Action states that the claims of Group III are classified in class 435, subclass 4, i.e., a single class. Furthermore, the peptides of Group II are also classified in as single class, i.e., class 530, subclass 350. That is, a single subclass covers all of the methods and a single subclass covers all of the mutants. Consequently, the search of the patent literature will clearly be the same for all of the mutants. Because the search of the scientific literature and patent literature will be identical for all of the mutants, there is no added burden concerning this aspect if all of the mutants are examined. Furthermore, the search will probably entail a computer search based on the mutant sequences in the sequence listing. It is believed that such a search would identify prior art directed to the claimed mutants. In fact, Applicants submit that such a search must have been performed with respect to the parent application, since all of the nucleic acid mutations were searched. The search of nucleic acid mutations in HERG would also yield the corresponding peptide mutations in HERG.

Consequently, it is submitted that the only reason for restriction is that the mutants are distinct from each other. But as explicitly stated in MPEP § 803, the inventions must be distinct and there must be a serious burden on the examiner. MPEP § 803.02 states that if a search and examination of an entire claim can be made without serious burden, the examiner must examine all claims on the merits, even though they are directed to independent and distinct inventions. As urged above, it is asserted that examination of all of the mutants with respect to Group III will not impose a serious burden.

In the event the requirement of 5 mutations is maintained, Applicants provisionally elect the following mutations for examination:

Cys at amino acid residue 572,

Asp at amino acid residue 588,

Val at amino acid residue 614,

Ala at amino acid residue 630, and

Leu at amino acid residue 29.

Claims 22-25 read on these mutations.

RESPECTFULLY SUBMITTED,					
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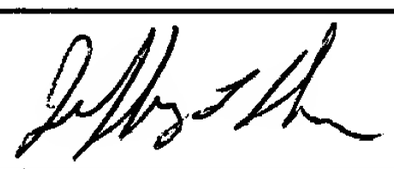
SIGNATURE			*DATE*	9 April 2002	
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